K121492

510(k) SUMMARY

SEP 11 2012

1.0 **Submitted By:**

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2.0 **Date Submitted:**

September 7, 2012

3.0 **Device Name(s):**

3.1 **Proprietary Names**
UniCel® DxC SYNCHRON® Systems Hemoglobin A1c- (HbA1c-) Reagent

3.2 **Classification Name**
Glycosylated hemoglobin assay 21 CFR § 864.7470 [LCP]
Calibrator for Hemoglobin or hematocrit measurement 21 CFR § 864.8165 [KRZ]

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
UniCel DxC Hemoglobin A1c (HbA1c-) Reagent	SYNCHRON Systems Hemoglobin A1c (HbA1c) Reagent	Beckman Coulter, Inc	K010748

5.0 **Description:**

The UniCel DxC SYNCHRON Systems Hemoglobin A1c- (HbA1c-) Reagent is intended for the quantitative determination of hemoglobin A1c concentration in human whole blood. The UniCel DxC Systems utilize two unique cartridges, Hb- and A1c-, to determine hemoglobin A1c concentration as a ratio of total hemoglobin.

Hb- reagent is used to measure total hemoglobin concentration by a colorimetric method. The system automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 8.6 parts

reagent. The system monitors the change in absorbance at 410 nanometers. This change in absorbance is directly proportional to the concentration of total hemoglobin in the sample and is used by the system to calculate and express total hemoglobin concentration.

A1c- reagent is used to measure the hemoglobin A1c concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies combine with hemoglobin A1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. The system automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 28 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is inversely proportional to the concentration of hemoglobin A1c in the sample and is used by the systems to calculate and express hemoglobin A1c concentration as a ratio of total hemoglobin.

6.0 Indications for Use:

The Hemoglobin A1c- reagent, when used in conjunction with UniCel® DxC 600/800 SYNCHRON® Systems, UniCel® DxC SYNCHRON® Systems HbA1c-Calibrators and SYNCHRON® and AU® Systems Hemolyzing Reagent, is intended for the quantitative determination of hemoglobin A1c concentration in human whole blood.

Measurement of hemoglobin A1c measures long-term glycemic control in patients with diabetes mellitus.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicate identified in Section 4.0 of this summary. Each modification was evaluated against the criteria for a Special 510(k) to insure that the particular change does not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Similarities		
DxC HbA1c- Reagent	Intended Use (clarification added)	
	Reagent components • Antibody Reagent • Polyhapten Reagent • Hemoglobin Reagent	
	Calibrator formulation	
	Calibrator traceability	
	Acceptable Anticoagulants	
	Specimen Stability	
	Analytical Range	
	Technology	
	Methodology	
	Kit configuration	
Differences		
DxC HbA1c- Reagent	Reagent and process optimization	The formulation and manufacturing process were improved. The reagent to sample ratio was refined.
	%HbA1c (NGSP) analytic range	Accepted calculated range reduced from 2 – 20% to 4 – 17%
	Sensitivity	Changed format to report out as LOD and LOB
	Reporting units	IFCC /IUPAC committee updated their recommendations on HbA1c units and nomenclature in 2007. HbA1c- is reported in NGSP% units and mmol/mol IFCC units.
	Stability	Claims have been updated
	Cal level 1	Changed from zero to non-zero level

8.0 Summary of Changes, Risk Analysis, Design Verification and Design Validation activities:

The UniCel DxC SYNCHRON Systems Hemoglobin A1c- reagent formulation and manufacturing process have been enhanced by the OEM manufacturer. The reagent to sample ratio and other DxC instrument parameters has been refined. The Calibrator level 1 was changed to a non-zero concentration utilizing the same matrix and manufacturing process as levels 2-5. Calibrator value-assignment process has been updated while maintaining traceability to IFCC reference method. New specifications and data were generated in support of these changes.

Risk Management Process for HbA1c-

- A Risk Management Plan was created to describe the various risk assessments required for the device modification and its components.
- A design risk assessment (Failure Modes & Effects Analysis or FMEA) was developed to identify potential risks on instrument parameter optimization, calibrator value assignment and system interaction associated with the device modification.
- A process FMEA was developed to identify potential risks related to manufacturing processes.
- A risk assessment on two software tolls for internal data analysis was developed to identify potential risks on the software's intended use.
- All risk assessments require that testing and reports (design verification, design validation and process validation) are complete before potential risks are mitigated.
- All safety-related risks (those that could potentially affect patient, bystander such as instrument operator, manufacturing personnel and field service engineer) from the various risk assessments are required to be transferred to a System Risk Assessment (SRA).
- A Comprehensive Risk Management Review meeting is required before a Risk Management Report is written.

Summary of Performance Studies

Area of Study	Test Protocols	Acceptance Criteria	Pass/Fail
Method Comparison	CLSI EP9A	Slope 1.0 ± 0.05 Intercept < ± 0.50 R ≥ 0.97	Pass
Analytic Sensitivity	CLSI EP17A	Total Hemoglobin (Hb-) LoD ≤ 6 g/dL (3.72 mmol/L) Hemoglobin A1c (A1c-) LoD ≤ 0.3 g/dL (0.19 mmol/L)	Pass
Linearity	CLSI EP6A	Recovery mean within (target) ±6% bias for Hb- ±6% bias %HbA1c- ±6% bias A1c- ≥0.4 g/dL ±15% bias for A1c- <0.4 g/dL	Pass
Precision	CLSI EP5A2	Within-run < 0.4 g/dL A1c- HbA1c %CV ≤ 5.0 %CV ≥ 0.4 g/dL A1c- HbA1c %CV ≤4.0%CV Total	Pass

Area of Study	Test Protocols	Acceptance Criteria	Pass/Fail
		≥ 0.4 g/dL A1c- HbA1c %CV ≤7.5%CV < 0.4 g/dL A1c- HbA1c %CV ≤4.0 %CV	
Reference Interval	CLSI C28-A3	90% of samples fall within reference range (4 - 6 %HbA1c NGSP)	Pass
Interferences	CLSI EP7-A2	No Significant Interference (within ± 6% mathematical)	Pass
Specificity	CLSI EP7-A2	Recovery within ±10% mathematical	Pass
Anticoagulants	Development procedures	Slope 1.0 ± 0.05 Intercept <± 0.75 r ≥ 0.97	Pass
Stability	Development procedures	Recovery of test samples is within ± 6%	Pass

Conclusion:

The UniCel DxC Systems Hemoglobin A1c- (HbA1c-) reagent is substantially equivalent to the predicate device, SYNCHRON Systems Hemoglobin A1c (HbA1c) reagent (K010748) for the quantitative determination of hemoglobin A1c concentration in human whole blood.

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Beckman Coulter, Inc.
c/o Annette Hellie
250 S. Kraemer Boulevard
M/S A2.SW.09
Brea, CA 92821

SEP 11 2012

Re: k121492
Trade Name: UniCel DxC Synchron® Systems Hemoglobin A1c (HbAlc-) Reagent
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Codes: LCP, KRZ
Dated: August 14, 2012
Received: August 15, 2012

Dear Ms. Hellie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K121492

Device Name: **UniCel DxC SYNCHRON® Systems Hemoglobin A1c- Reagent**

Indications for Use:

The Hemoglobin A1c- reagent, when used in conjunction with UniCel® DxC 600/800 SYNCHRON® Systems, UniCel® DxC SYNCHRON® Systems HbA1c- Calibrators and SYNCHRON® and AU® Systems Hemolyzing Reagent, is intended for the quantitative determination of hemoglobin A1c concentration in human whole blood.

Measurement of hemoglobin A1c measures long-term glycemic control in patients with diabetes mellitus.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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